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EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

This office action is a clarification of the non-final rejection dated 4/21/09, specifically the status of all the claims: All pending claims are rejected under the 103 rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 and 78-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not support the amendment "the free end is proximal of the fixed end" the examiner believes this should be "the free end is distal of the fixed end".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-34 and 78-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modesitt et al. (U.S. Patent No. 6,136,010) in view of Kuehn et al. (US 6165183).

Modesitt teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an elongate body (12) having a proximal and a distal end; the elongate body having housed therein a fastening material (34) configured to suture two heart leaflets together (capable of being used in the heart, Fig. 11D); an anchor zone (22) on a distal portion of the body, and at least one tissue manipulator (24) carried by the flexible body proximally of the anchor zone (Fig. 5), the tissue manipulator having a fixed end (col. 9, ll. 1-3, each half of the tissue manipulators are affixed together) and a free end (ends near 52 in Fig. 12B), the free end being moveable to an extended position in which the free end is proximal of the fixed end (Fig. 13), the tissue manipulator being disposed at an angle not more than 90 degrees with respect to the elongate flexible body when in the extended position (Fig. 13E); the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator (440) can be positioned at the valve (Fig. 21).
- A fastening material adapted for use in suturing two leaflets of a heart, the fastening material being housed within the distal portion
- The minimum length of the anchor zone is at least 10 cm (col. 8, ll. 5,6 using the needles as a reference the anchor zone is clearly at least 10 cm).

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- wherein the tissue manipulator is moveable between an axial orientation (Fig. 12A) for transluminal navigation and an inclined orientation (Fig. 12B) for manipulating tissue.
- wherein the first tissue manipulator (24) comprises a tissue grasper (38) for grasping a heart valve leaflet.
- at least a first component (24), which is axially moveable with respect to a second component (Fig. 12B)
- at least one needle capturing device coupled with the end of the fastening material (Fig. 13E)
- the fastening material is partially housed within the tissue manipulator (Fig. 13E) and distal the tissue manipulator (Fig. 13E)
- the catheter having a length sufficient to reach the heart from a femoral vein access
- the first and second tissue manipulators (as shown when in use in Fig. 13E) are asymmetric, the first tissue manipulator is longer than the second tissue manipulator (see Fig. 13E)
- a two receptacle located within the first and second tissue manipulators for receiving a first/second fixating member (52, Fig. 12B)
- a first end of a fastening material is coupled with the first receptacle and a second end of the fastening material is coupled with the second receptacle (resulting in Figs. 13 E and F)

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- the tissue manipulator comprises a first elongate tissue manipulator having a first length and a second tissue manipulator having a second length (as seen in Fig. 13E), the first and second tissue manipulators both configured to engage portions of a heart valve from the same side of the valve, the second length being greater than the first length (capable of being used as described)

Modesitt teaches the claimed invention as described above but is silent regarding the material choice for the shaft, 12. However Cribier teaches an interventional catheter for accessing the heart wherein elongate body is flexible (Fig. 8) and is configured to bend in order to access the heart and bend through the arteries. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Modesitt with flexible body of Cribier in order to access a wide variety of medical problems that require passage through tortuous pathways in the body.

Response to Arguments

Applicant's arguments filed 2/6/08 have been considered, but are moot in view of new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is

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(571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773